Meeting Minutes: FDA and Medtronics

Date: July 27, 2000 11-12 noon
Location: 9200 Corporate Blvd., Rockville, MD 20850 Room 330 V
Type of Meeting: Reclassification issues for implantable spinal cord stimulators
Lead Reviewer: Kristen Bowsher, Ph.D.
Device: Totally Implantable spinal cord stimulator for treatment of chronic, intractable pain

FDA Attendees:	Medtronic Attendees:
Celia Witten, M.D. Ph.D., Div Director, DGRND	Lynn Switzer, Dir. RA/RA Neurostimulator
Russ Pagano, Ph.D., Branch Chief, REDB	Clifton Owens, VP, Gen Mgr: Neurostimulators
Janet Scudiero, Exec Sec, Neuro Panel, DGRND	Kevin Kelly, Dir., Product Development
Natalie Tudor, Consumer Safety Officer, DGRND	Kathy Jo Fahey, Prin. Prod Reg. Mgr.
Nancy Pluhowski, Office Center Director	Amanda Klosterman, Legal Counsel
Heather Rosecrans, ODE, POS/510(k)	
Marjorie Shulman, ODE, POS	
Joseph Sheehan, Chief, Regs/ OHIP	Richard Simpson, M.D., Ph.D.
Kristen Bowsher, Ph.D., Reviewer, REDB	Mark Heller, LLP, Hale and Dorr

Medtronics provided handout of slides and presented overview of manufacturing elements for insuring safety of device and differences between RF and IPG devices. Sponsor maintained that these differences should require preapproval inspections. Sponsor referred to FDA Panel last fall, which sponsor felt was misinformed due to irregularities in proceedings. Sponsor then presented summary of opposition to changing implantable spinal cord stimulators from current Class III to Class II.

Dr. Simpson presented clinical validation and reasons for not changing classification.

FDA question to Dr. Simpson: What are the relevant failure modes for these devices?

Dr. Simpson:
- Output too high and patient could not stop because infirm
- Leakage into surrounding tissue
- Output not accurate and patient not receiving immediate attention
- Fibrous granuloma forming making it difficult to remove or repair
- Deep Brain Stimulation (DBS) anecdotes, including death

Mark Heller, Hale and Dorr , argued case for company to keep current classification and a change would be ill-advised.

Summary:

Medtronics asked FDA not to accept Panel's recommendation.

FDA stated that petition to reclassify implantable spinal cord stimulators is still under review; no final decision has been reached. FDA is taking Medtronics advisement under consideration.

Prepared by Natalie Tudor:
Consumer Safety Officer, DGRND — Natalie Tudor

Kristen Bowsher, Ph.D., Lead Reviewer — Kristen Bowsher

Russ Pagano, Ph.D. ,Branch Chief, REDB — Russell Pagano

OOD-1455

OOP-0788

MM2

Meeting Minutes: FDA and ANS

Company: ANS
Meeting Date: May 18, 2000 2-3:00 pm
Location: 9200 Corporate Blvd., Rockville, MD 20850 - Room 200V
Type of Meeting: Reclassification of Totally Implantable Spinal Cord Stimulators
Background: ANS has filed petition to reclassify devices from Class III to Class II

FDA Attendees:

Celia Witten, M.D. PhD, Div. Dir, DGRND
Russ Pagano, Ph.D., Branch Chief, REDB
Janet Scudiero, Exec. Sec., Neuro Panel
Kristen Bowsher, Ph.D., Reviewer, REDB
Joseph Sheehan, Chief, Regs, OHIP
Natalie Tudor, Consumer Safety Officer, DGRND

ANS Attendees;

Chris Chavez, President
Drew Johnson, Dir., Regulatory Affairs
Larry R. Pilot, LLP, McKenna and Cuneo

Type of Meeting: To determine status of ANS petition to FDA to reclassify implantable spinal cord Stimulators from Class III to Class II.

Sponsor presented overview of market with Medtronic-80%, ANS-7% and Cyberonics-10%. Sponsor reviewed meeting with FDA Feb 1999 stating RF and IPG equivalent, except one with battery inside and other outside.

FDA: Reclassification petition was an option for the sponsor; devices are similar but not necessarily equivalent. FDA's position is the February letter is still valid; FDA has enough information but has not made a decision on reclassification to Class II. Regarding special controls, FDA does not have new "special controls" at this time. As FDA goes through the decision process the company may be asked for more information but the next step is to continue to review.

FDA has to publish Panel recommendation and get comments. Since there was a split Panel (5-1) there are questions and issues.

Even though under review FDA cannot share with sponsor- where we are in the review process but appreciates the sponsor telling FDA where they are.

Since FDA laid out options a year ago; implantable spinal cord stimulators have already been determined Class III , therefor, do not see "de nova" as a regulatory route for sponsor.

Sponsor: Sponsor requests suggestions for company to have a process to market an IPG. An option of company is to pursue litigation that FDA is not in compliance with Act. Sponsor stated that statute has a time course and now in Day-360-400.

FDA: FDA could advise sponsor, instead of looking at 510(k) and PMA, as to what things go into a Class II 510(k) since sponsor will have to address either way. Sponsor's plan to address additional risks is good.

FDA asked sponsor to relook at petition and revisit special controls and these can be added. If sponsor is comfortable going 510(k) route--if reclassified--the entire class of products (devices of same generic type) would automatically become predicates.

Sponsor: Sponsor is trying to find the least burdensome path. Plans are to launch device in Europe the third quarter of this year. Sponsor would be prepared to do a 510(k) by June 15th, only missing FDA's special controls.

Summary:

FDA will take back the list of what sponsor can provide and see if there are any other things sponsor can add. Sponsor will communicate with Dr. Bowsher after FDA looks at list.

In the process of reclassification FDA does not see that sponsor's submitting a 510(k) now would be a good choice.

Process has been an open process with Panel /dockets

Prepared by Natalie Tudor
Consumer Safety Officer, DGRND

Natalie Tudor

Kristen Bowsher, Ph.D.
Lead Reviewer

Kristen Bowsher

Russ Pagano, Ph.D.
Branch Chief, REDB

Russ Pagano